30 April 2020
EMA/CHMP/219873/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Suboxone

buprenorphine / naloxone

On 30 April 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Suboxone. The marketing authorisation holder for this medicinal product is Indivior Europe Limited.

The CHMP adopted a new pharmaceutical form (sublingual film) associated with four new strengths (2/0.5, 4/1, 8/2, and 16/4 mg) for either sublingual or buccal use. The new formulation adds additional safety features to prevent intravenous misuse.

For information, the full indications for Suboxone sublingual film will be as follows:

> Substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter intravenous misuse. Suboxone is indicated in adults and adolescents over 15 years of age who have agreed to be treated for addiction.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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